

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 6481-6500

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its quality fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article.

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6481. *Delfetamine Stedytabs and Delfeta-Sed Stedytabs*. (F.D.C. No. 44603. S. Nos. 4-020/1 R.)

QUANTITY: 2 drums, each containing about 50,000 tablets, and 118 30-tablet ctns., of *Delfetamine Stedytabs*, and 278 30-tablet ctns., of *Delfeta-Sed Stedytabs*, at Baltimore, Md., in possession of Eastern Research Laboratories, Inc.

SHIPPED: Between 11-16-58 and 3-21-60, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Drum) "Delfetamine, 30 Mg. Stedytabs Each tablet contains: \*Delfetamine 30 mg. Caution \* \* \* Average dose \* \* \* Manufactured by a special process \* \* \* to provide prolonged continuous therapeutic effect from active ingredient over a period up to 8-12 hours. \*Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. Victor M. Hermelin and Company, New Products Division of K-V Pharmacal Company, St. Louis 17, Missouri"; (ctn.) "Stedytabs Sustained Release Tablets Delfetamine dextro-levo N-methylamphetamine HCl \* \* \* Eastern Research Laboratories, Inc., Baltimore 1, Maryland"; and "Stedytabs Sustained Release Tablets Delfeta-sed Delfetamine With Sedafax \* \* \* Eastern Research Laboratories, Inc., Baltimore 1, Maryland."

**RESULTS OF INVESTIGATION:** Examination showed that the articles contained (*Delfetamine Stedytabs*) methamphetamine HCl, and (*Delfeta-Sed Stedytabs*) methamphetamine HCl and amobarbital. The tablets in the cartons were repacked by the dealer from bulk stock shipped as described above.

**LIBELED:** 6-3-60, Dist. Md.

**CHARGE:** 502(d)—while held for sale, the *Delfeta-Sed Stedytabs* contained a habit forming drug, amobarbital, a derivative of barbituric acid, and their label failed to bear the name of the drug and in juxtaposition therewith the statement "Warning—May be habit forming"; and 505(a)—the *Delfetamine Stedytabs* and the *Delfeta-Sed Stedytabs* were new drugs which may not be introduced into interstate commerce since applications filed pursuant to the law were not effective with respect to such drugs.

**DISPOSITION:** 8-8-60. Default—destruction.

**6482. Meprobamate tablets, chlorothiazide tablets, and hydrochlorothiazide tablets.** (F.D.C. No. 44875. S. Nos. 4-661/2 R, 4-664 R.)

**QUANTITY:** Unknown quantities of the above-mentioned drugs at Washington, D.C., in possession of Discount Drugs.

**LIBELED:** 8-30-60, Dist. Columbia.

**CHARGE:** *Meprobamate tablets*, 502(i) (2)—while in interstate commerce, the article was an imitation of another drug, namely, Miltown tablets; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Miltown tablets.

*Chlorothiazide tablets*, 502(i) (2)—while in interstate commerce, the article was an imitation of another drug, namely, Diuril tablets; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Diuril tablets.

*Hydrochlorothiazide tablets*, 502(i) (2)—while in interstate commerce, the article was an imitation of another drug, namely, Hydrodiuril tablets; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Hydrodiuril tablets.

All articles, 505(a)—the articles were new drugs which may not be introduced into interstate commerce since applications filed pursuant to 505(b) were not effective with respect to such drugs.

**DISPOSITION:** 10-5-60. Default—delivered to the Food and Drug Administration.

**VIOLATIVE SALES OF PRESCRIPTION DRUGS**

**6483. Phenobarbital tablets and amphetamine sulfate tablets.** (F.D.C. No. 44941. S. Nos. 61-603/6 P, 61-608/12 P, 61-614 P, 61-616/8 P.)

**INFORMATION FILED:** 11-28-60, N. Dist. Ohio, against William H. Caine, M.D., Antwerp, Ohio.

**SHIPPED:** Between 5-30-59 and 7-18-59, from Ohio to Michigan.

**CHARGE:** 502(f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purposes and conditions for which they were intended; and 503(b) (1)—the articles were drugs within the meaning of such section, and while being held for sale by the defendant, were dispensed by the defendant without a prescription.

**PLEA:** Guilty.

**DISPOSITION:** 12-16-60. \$325 fine and probation for 1 year.